



DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License: Multi-Domain Amphipathic Helical Peptide For Use As A Human Therapeutic In Patients With Atherosclerotic Cardiovascular Disease, Including Patients Undergoing Cardiovascular Surgery Who Are At Risk Of Acute Kidney Injury

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Heart, Lung, and Blood Institute, an institute of the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive patent license to Phyxius Therapeutics, Inc., a start-up company incorporated as a C corporation under the laws of the state of Delaware, to practice the inventions covered by the patent estate listed in the Supplementary Information section of this notice. This is a first notice intended to apprise the public of a change in prospective licensee of the subject intellectual property rights in the stated field of use.

DATES: Only written comments and/or applications for a license which are received by the National Heart, Lung, and Blood Institute on or before **[INSERT DATE 15 DAYS FROM DATE OF PUBLICATION OF NOTICE IN THE FEDERAL REGISTER]** will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, and comments relating to the contemplated an exclusive patent license should be directed to: Michael Davis, J.D., Ph.D., Senior Technology Transfer Manager, 31 Center Drive Room 4A29,

MSC2479, Bethesda, MD 20892-2479, phone number 301-451-9032, or

michael.davis4@nih.gov.

SUPPLEMENTARY INFORMATION:

Intellectual Property

NIH REF NO.	TITLE	PATENT APPLICATION NO.	FILING DATE	ISSUED PATENT NO.	ISSUE DATE
E-114-2004-0-US-01	Multi-Domain Amphipathic Helical Peptides And Methods Of Their Use	60/619,392	10/15/04		
E-114-2004-0-PCT-02	Multi-Domain Amphipathic Helical Peptides And Methods Of Their Use	PCT/US2005/	10/14/05		
E-114-2004-0-AU-03	Multi-Domain Amphipathic Helical Peptides And Methods Of Their Use	2005295640	10/14/05	2005295640	11/10/11
E-114-2004-0-CA-04	Multi-Domain Amphipathic Helical Peptides And Methods Of Their Use	2584048	10/14/05	2584048	08/09/16
E-114-2004-0-EP-05	Multi-Domain Amphipathic Helical Peptides And Methods Of Their Use	05815961.7	10/14/05	1812474	05/26/10
E-114-2004-0-JP-06	Multi-Domain Amphipathic Helical Peptides And Methods Of Their Use	2007-536912	10/14/05	5,091,679	09/21/12
E-114-2004-0-US-07	Multi-Domain Amphipathic Helical Peptides And Methods Of Their Use	11/577,259	04/13/07	7,572,771	08/11/09
E-114-2004-0-US-08	Multi-Domain Amphipathic Helical Peptides And Methods Of Their Use	12/497,443	07/02/09	8,071,746	12/06/11
E-114-2004-0-US-09	Multi-Domain Amphipathic Helical Peptides And Methods Of Their Use	12/766,761	04/23/10	8,148,323	04/03/12
E-114-2004-0-CH-11	Multi-Domain Amphipathic Helical Peptides And Methods Of Their Use	05815961.7	10/14/05	1812474	05/26/10
E-114-2004-0-DE-12	Multi-Domain Amphipathic Helical Peptides And Methods Of Their Use	05815961.7	10/14/05	1812474	05/26/10
E-114-2004-0-ES-13	Multi-Domain Amphipathic Helical Peptides And Methods Of Their Use	05815961.7	10/14/05	1812474	05/26/10
E-114-2004-0-FR-14	Multi-Domain Amphipathic Helical Peptides And Methods Of Their Use	05815961.7	10/14/05	1812474	05/26/10
E-114-2004-0-GB-15	Multi-Domain Amphipathic Helical Peptides And Methods Of Their Use	05815961.7	10/14/05	1812474	05/26/10
E-114-2004-0-IT-16	Multi-Domain Amphipathic Helical Peptides And Methods Of Their Use	05815961.7	10/14/05	1812474	05/26/10
E-114-2004-0-US-17	Multi-Domain Amphipathic Helical Peptides And Methods Of Their Use	13/407,132	02/28/12	8,835,378	09/16/14

All U.S. and foreign patents and applications claiming priority to any member of the above.

The patent rights in these inventions have been assigned or exclusively licensed to the Government of the United States of America.

The prospective exclusive license territory may be worldwide and in fields of use that may be limited to use as a human therapeutic in patients with atherosclerotic cardiovascular disease (ASCVD), including patients undergoing cardiovascular surgery who are at risk of acute kidney injury.

The patents listed above cover an invention directed to peptides or peptide analogs with multiple amphipathic alpha helical domains that promote lipid efflux from cells via an ABCA1-dependent pathway. This invention is also directed to methods of identifying non-cytotoxic peptides that promote ABCA1-dependent lipid efflux from cells, and to methods of using multi-domain amphipathic alpha helical peptides or peptide analogs to treat or inhibit dyslipidemic disorders.

This notice is made in accordance with 35 U.S.C. 209 and 37 CFR part 404. The prospective exclusive license will be royalty bearing. The prospective exclusive license may be granted unless within fifteen (15) days from the date of this published notice, the National Heart, Lung, and Blood Institute receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR part 404.

In response to this Notice, the public may file comments or objections. Comments and objections, other than those in the form of a license application, will not be treated confidentially, and may be made publicly available.

License applications submitted in response to this notice will be presumed to contain business confidential information and any release of information in these license applications will be made only as required and upon a request under the Freedom of Information Act, 5 U.S.C. 552.

Bruce D. Goldstein,

Director,

Office of Technology Transfer and Development,

National Heart, Lung, and Blood Institute.

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